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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,670	02/09/2004	Ramez Emile Necola Shehada	064693-0097	1453

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EXAMINER
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GIBSON, KESHIA L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/775,670

Applicant(s)

NECOLA SHEHADA, RAMEZ  
EMILE

Examiner

Keshia Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/15/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 12/5/05 have been fully considered but they are not persuasive.
2. In response to applicant's argument that Johnson does not disclose a draining function, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Furthermore, as pointed out by applicant, the catheter of Johnson may be coupled with an element, including a syringe, to remove blood from a body cavity, and is therefore capable of draining a body cavity. It is further pointed out that a catheter, by definition, is a tube inserted into a body cavity for introduction or withdrawal of fluids (see attached definitions).
3. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Johnson teaches a surgical device for drawing bodily fluids into a conduit or tube; Russo teaches a

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surgical device for drawing bodily fluid into a conduit or tube. As stated in the previous Office Action, Russo goes on to teach that providing a plurality of holes in the tube wall to affect the manner in which fluid passes/flows into the tube. This provides motivation to modify the device of Johnson to provide for a plurality of holes in the tube wall.

4. Any other arguments with respect to claims 2-14 have been considered but are moot in view of the new ground(s) of rejection.

### ***Drawings***

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, 1) a surgical drain having a fiber optic with a branched distal end branches from the conduit and a plurality of drain holes and 2) a surgical drain having a fiber optic with a branched distal end branches and further comprising third and fourth optical fibers must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

6. The abstract of the disclosure is objected to because the implied language "Disclosed are." it is suggested that the language be removed; again, no replacement language is required. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 3,866,599).

In regard to Claims 16-17, Johnson discloses a surgical drain 1 comprising an elongated conduit 2 configured to be implanted in and to drain from a body cavity (column 1, lines 7-10). The drain 1 further comprises an energy source (optical fibers)

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11, 21, 27 and an energy receiver (optical fibers) 11, 21, 27 (column 1, lines 20-25 and lines 44-49; column 2, lines 12-22 and lines 51-66).

In regard to Claims 18-19, the fibers are embedded in the conduit.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-6, 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view Polanyl (US 3,674,013).

In regard to Claim 1, Johnson discloses a surgical drain 1 comprising an elongated conduit 2 configured to be implanted in and to drain from a body cavity (column 1, lines 7-10; column 2, lines 12-28). The drain 1 further comprises a first optical fiber 11, 21, 27 and a second optical fiber 11, 21, 27; the fibers are configured to transmit and receive energy from body tissue (column 1, lines 20-25 and lines 44-49; column 2, lines 12-22

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and lines 51-66). Johnson discloses multiple optical fibers, any of which may be considered a first optical fiber and a second optical fiber. Johnson does not expressly disclose that the first distal end of the first optical fiber branches from the conduit. Polanyi teaches a fiber optic catheter with light emitting and light receiving optical fibers. Polanyi further teaches that the fibers are directed at an angle to one side of the catheter wall so that the optical fiber remains spaced from the body organs; and, as a result, this reduces the chance of unreliable or false readings from the body organ or cavity. One of ordinary skill in the art would have been motivated to branch the distal end of the first optical fiber from the conduit since having the fiber bend away from (branch from) the conduit allows the fiber to remain spaced from the body organ, thereby reducing the likelihood of inaccurate readings from the body cavity and organs. Thus, it would have been obvious to one of ordinary skill in the art to modify to branch the distal end of the first optical fiber of Johnson from the conduit since having the fiber bend away from (branch from) the conduit allows the fiber to remain spaced from the body organ, thereby reducing the likelihood of inaccurate readings from the body cavity and organs, as taught by Polanyi.

In regard to Claim 2, Johnson discloses that the optical fibers extend substantially parallel to each other; thus the distal ends of the optical fibers are substantially parallel to each other (Figs. 2-3 and 6).

In regard to Claim 3, Johnson discloses that the distal ends of the optical fibers are configured for insertion into tissue (column 2, lines 29-50).

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In regard to Claim 4, Polanyi discloses a housing (collar 8) extending (inwardly) from the conduit supporting the fibers for insertion into a body (column 2, lines 17-23; Fig. 3).

In regard to Claims 5-6, Johnson discloses that the drain comprises a sensing system that can sense physiological properties, including oxygenation and pressure (column 1, lines 44-49; column 2, lines 16-22 and 33-36).

In regard to Claim 8, the fibers are embedded within the conduit (Johnson, Figs., column 3, lines 6-9).

In regard to Claim 9, Johnson discloses that the drain further comprises an oximeter that receives energy from the optical fibers 11, 21, 27 (column 2, line 62-column 3, line 5). The oximeter provides measurements, so it would have to display these measurements in some form to the user. Thus, the oximeter is considered analogous to a display.

In regard to Claim 10, Johnson discloses that the drain may further comprise third and fourth optical fibers 11, 21, 27 configured to deliver energy to and receive energy from tissue (column 1, lines 20-25 and lines 44-49; column 2, lines 12-22 and lines 51-68). Johnson discloses multiple optical fibers, any of which may be considered a third optical fiber and a fourth optical fiber.

In regard to Claim 11, the energy received by the second and fourth (light-receiving) fibers is compared to that energy transmitted by other (light-emitting) fibers to obtain a ratio (column 2, line 51-column 3, line 5); therefore, the energy received by these fibers is compared.



In regard to Claim 12, the optical fiber 11, 21, 27 includes a component (such as surface or a distal end or any other portion of the fiber itself) affixed to the conduit 2 (Figs. 2-6; column 3, lines 6-9).

In regard to Claim 13, as discussed for Claim 8, Johnson discloses that the optical fiber 11, 21, 27, and therefore a component of the fiber, is embedded in the conduit (column 3, lines 6-9). Also see discussion for Claim 12.

In regard to Claim 14, as discussed for Claims 5-6, Johnson discloses that the component 11, 21, 27 can sense physiological properties, such as oxygenation; therefore the component 11, 21, 27 comprises a sensor (column 1, lines 44-49; column 2, lines 16-22 and 33-36).

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Polanyi as applied to claims 1-6 and 8-14 above, and further in view of Russo et al. (US 4,317,452).

In regard to Claim 7, as discussed previously, Johnson et al. in view of Polanyi disclose the claimed invention but do not expressly disclose that the conduit comprises a plurality of holes spaced along substantially the entire length of the drain portion. Russo et al. discloses a surgical drain comprising a conduit 10 having a plurality of holes along substantially the entire length of the drain portion (Fig. 1; column 2, lines 7-19; column 4, line 56-column 5, line). Russo et al. teach that having holes along a substantial portion of the conduit 10 allows body fluids in the cavity to pass into and along the conduit into a drainage site. One of ordinary skill in the art would have been motivated

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to provide Johnson in view of Polanyl with a plurality of holes in the tube wall to affect the manner in which fluid passes/flows into the tube. Thus, it would have been obvious to one of ordinary skill in the to provide the surgical drain of Johnson in view of Polanyl with a plurality of holes, as taught by Russo et al., since doing so would allow for body fluid to be drained from a body cavity along a substantial length of the tube and/or from a substantial portion of the body cavity.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Russo (4,523,920), Martin (US 4,631,061), Melinyshyn et al. (US 4,925,452), Evans (US 4,697,593), Doi (US 4,971,034), and Richardson (WO 03/105942).

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keshia Gibson whose telephone number is (571) 272-7136. The examiner can normally be reached on M-F 8:30 a.m. - 6 p.m., out every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Keshia Gibson  
Examiner  
Art Unit 3761

klg 12/18/05

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER  
